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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,001	09/26/2005	Medasani Munisekhar	VISH0101PUSA	1418
22045	7590	02/03/2009	EXAMINER	
BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075			CHEN, CATHERYNE	
			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,001	<b>Applicant(s)</b> MUNISEKHAR, MEDASANI	
	<b>Examiner</b> CATHERYNE CHEN	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Currently, Claims 16-29 are pending. Claims 16-29 are examined on the merits. Claims 1-15 are canceled.

#### ***Election/Restrictions***

Applicant's election without traverse of the species ammonium chloride, keratolytic composition, psoriasis, benzalkonium chloride in the reply filed on Oct. 23, 2008 is acknowledged.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 16-29 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 16, the amount of vanilla is less than 2%. This is interpreted to include 0% because zero is less than two. Therefore, the limitation of "less than 2%" does not make sense for one to include the ingredient vanilla in the composition. Please set a specific lower limit for vanilla in order for vanilla to be included as an active ingredient in the composition.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 18, 21, 25-26, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by McAtee et al. (US 5607980).

McAtee et al. teaches a topical composition comprising from about 0.1-15% by weight of a cationic surfactant (Claim 1). Cationic surfactant can be stearamidopropyl dimethyl ammonium chloride (column 8, lines 33, 43-44) and quaternary ammonium salt cetyl ammonium chloride (column 8, lines 46, 48). A composition wherein dilauryl dimethyl ammonium chloride, distearyl dimethyl ammonium chloride, dimyristyl dimethyl

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ammonium chloride, dipalmityl dimethyl ammonium chloride, and mixtures thereof (Claim 13). The composition can be formulated into creams, lotions, mousses, sprays, cleansers, bars, gels, and the like (column 4, lines 4-7).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-22, 25-26, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trage et al. (US 2002/0111280 A1).

Trage et al. teaches a care agent, which comprises matrix particles having a perfume component and a washing-active surfactant component, care agents can be used in body-cleansing (paragraph 0001). Matrix particles can be prepared by dissolving a multifunctional polysaccharide in water (paragraph 0012), vanilla extract

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(paragraph 0022), ammonium chloride (paragraph 0063), 0.1 to 50 parts by weight of washing-active surfactant component (paragraph 0060), 0.1 to 5 parts by weight of electrolytes (paragraph 0064), as shower gel (paragraph 0079), fillers (Claim 23). However, it does not teach the claimed concentrations.

The reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

The reference also does not specifically teach adding the ingredients in the amounts claimed by applicant. The reference does teach a body-cleansing medicament (paragraph 0001) at 0.1 to 50 parts by weight of washing-active surfactant component (paragraph 0060), 0.1 to 5 parts by weight of electrolytes (paragraph 0064). The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus,

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absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 16-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoll et al. (US 4822604), Figueroa (WO 99/32084), Durr et al. (US 5997889), McAtee et al. (US 5607980).

Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp (Abstract) with 1.00%, 1.50%, 0.75% ammonium chloride (column 4, line 43) and keratolytic stabilizing agent (column 5, line 8), pH range of about 3.0-6.5 (Claim 3). A method of treating psoriasis of the scalp (Claim 7). Keratolytic agents at about 1.8-3.0% by weight of the composition (Claim 7, b) and about 0.25-20% by weight of a tertiary amine keratolytic stabilizing agent (Claim 7, c). However, it does not teach benzalkonium chloride, vanilla, and the claimed concentrations.

Figueroa teaches a composition for topical application of skin for psoriasis (page 3, line 6) with benzalkonium chloride from pH 3.5-4.5 (page 4, lines 23-26) at 50% benzalkonium chloride or 0.2 g (page 12, line 25).

Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55) as a cream (Abstract).

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McAtee et al. teaches composition for application to human skin for psoriasis (column 1, lines 37-38) with about 0.1-15% by weight of a cationic surfactant (column 3, lines 21-22), humectants with quaternary alkyl ammonium from about 0.1-20% (column 13, lines 42-50).

Ammonium chloride, benzalkonium chloride, vanilla extract are all used on skin to treat psoriasis (see discussion above). Thus, an artisan of ordinary skill would reasonably expect that Ammonium chloride, benzalkonium chloride, vanilla extract could be used as the types composition to treat a skin condition, specifically psoriasis, taught by the references. This reasonable expectation of success would motivate the artisan to use ammonium chloride, benzalkonium chloride, vanilla extract in the reference composition. Thus, using ammonium chloride, benzalkonium chloride, vanilla extract is considered an obvious modification of the references.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. However, the references do teach the composition for treating psoriasis. McAtee et al. teaches composition for application to human skin for psoriasis (column 1, lines 37-38) with about 0.1-15% by weight of a cationic surfactant (column 3, lines 21-22), humectants with quaternary alkyl ammonium from about 0.1-20% (column 13, lines 42-50). Quaternary alkyl ammonium can include benzalkonium chloride (see Applicant's claim 24). Cationic surfactant can include ammonium chloride (see Applicant's claim 17). Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55). The amount of a specific ingredient in a composition that is used for a particular purpose



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(the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen  
Examiner Art Unit 1655

/Michael V. Meller/  
Primary Examiner, Art Unit 1655